

**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA**

In re: BAIR HUGGER FORCED AIR
WARMING DEVICES PRODUCTS
LIABILITY LITIGATION

MDL No. 15-2666 (JNE/FLN)

This Document Relates to All Actions

**DEFENDANTS’
MASTER ANSWER TO
PLAINTIFFS’ MASTER LONG
FORM COMPLAINT AND JURY
DEMAND**

Defendants 3M Company and Arizant Healthcare Inc. (collectively “3M”) submit this Master Answer in response to Plaintiffs’ Master Long Form Complaint and Jury Demand (“Master Complaint”) as follows:

PRELIMINARY STATEMENT

By way of general response, 3M denies the allegations in Plaintiffs’ Master Complaint and denies that the 3M™ Bair Hugger™ patient warming system (“Bair Hugger system” or “Bair Hugger warming blanket”) caused injury or damage to Plaintiffs. Not one scientific study (including those studies cited in the Master Complaint) has ever concluded that the Bair Hugger system actually causes or increases the risk of post-operative surgical site infections. Multiple randomized, controlled clinical trials have found that the use of Bair Hugger warming blankets keep patients warm and thereby provide a host of benefits to patients, including decreased post-operative heart attacks, reduced surgical

bleeding, shortened recovery time, improved patient comfort, and reduced risk of infection.

To the extent the allegations in the Master Complaint are incorporated into all complaints previously filed directly in or transferred to this MDL proceeding, as well as any complaints that may in the future be filed directly in or transferred to this MDL proceeding, 3M's Master Answer is intended to respond to the same.

INTRODUCTION¹

1. 3M admits that Plaintiffs' lawsuit involves the Bair Hugger system. Except as thus stated, 3M denies the remaining allegations in Paragraph 1.

2. 3M admits that it manufactures and distributes the Bair Hugger system. 3M also admits that Arizant Healthcare Inc., at certain times in the past, manufactured and distributed the Bair Hugger system. Responding further, 3M admits that tens of thousands of patients in hospitals across the U.S. undergo surgery each month involving intraoperative use of the Bair Hugger system. 3M further avers that over 200 million patients have been safely and effectively warmed using the Bair Hugger system and that there has not been a single verified case of infection caused by the Bair Hugger system. Except as expressly admitted, 3M denies the allegations in Paragraph 2.

3. 3M admits only that the Bair Hugger system consists of a portable warming unit which draws ambient air through a filter and warms the air to a

¹ Headings and subheadings throughout this Answer are taken directly from the Master Complaints and are included solely for ease of reference. They do not constitute admissions, and any portion of a heading or subheading that may be construed as a factual allegation is specifically denied.

specified temperature, then delivers the warmed air through a flexible hose to a single use disposable blanket – containing small perforations – with the perforated side of the disposable blanket placed either over or in some cases under the patient to provide warm air to the patient, including during surgery. Except as thus stated, 3M denies the remaining allegations in Paragraph 3.

4. 3M denies the allegations in Paragraph 4.

5. 3M denies the allegations in Paragraph 5.

6. 3M denies the allegations in Paragraph 6.

7. 3M denies the allegations in Paragraph 7.

8. 3M denies the allegations in Paragraph 8.

9. Plaintiffs' allegations in Paragraph 9 appear to seek to characterize a writing. In response, 3M states that such writings speak for themselves, and 3M denies that such writings have been completely or accurately characterized. Except as thus stated, 3M denies the remaining allegations in Paragraph 9.

10. 3M admits only that it has actively marketed the Bair Hugger system as safe and effective in both general and orthopedic surgeries. Responding further, 3M incorporates its Preliminary Statement by reference. Except as thus stated, 3M denies the remaining allegations in Paragraph 10.

11. 3M denies the allegations in Paragraph 11.

12. 3M responds that the regulatory filings with FDA for the various models of the Bair Hugger system include certain references to the air filtration

system and speak for themselves. Responding further, to the extent Paragraph 12 contains a legal or regulatory conclusion, no response is required. 3M admits that the air filters sold for use with the marketed Bair Hugger systems were not HEPA filters. Except as thus stated, 3M denies the remaining allegations in Paragraph 12.

13. 3M admits the filter media for certain models of the Bair Hugger system were changed in 2009. 3M denies the remaining allegations in Paragraph 13.

14. 3M denies the allegations in Paragraph 14.

15. 3M denies the allegations in Paragraph 15.

16. 3M denies the allegations in Paragraph 16.

17. 3M denies the allegations in Paragraph 17.

18. 3M denies the allegations in Paragraph 18.

19. 3M denies the allegations in Paragraph 19.

20. 3M denies the allegations in Paragraph 20.

21. 3M denies the allegations in Paragraph 21.

PARTIES

22. 3M is without sufficient information or knowledge to admit or deny that Plaintiffs are residents and/or citizens of the United States. Except as thus stated, 3M denies the remaining allegations of Paragraph 22.

23. 3M admits the allegations in Paragraph 23.

24. 3M avers that Arizant Healthcare Inc. was a Minnesota corporation with its principal place of business in Minnesota. Responding further, 3M admits that Arizant Healthcare Inc. was a wholly owned subsidiary of 3M or one of its wholly owned subsidiaries. Responding further, 3M avers that Arizant Healthcare Inc. was entirely dissolved in December 2014. Except as thus stated, 3M denies the remaining allegations in Paragraph 24.

25. 3M admits that in 2010, 3M entered into an agreement to acquire Arizant, Inc. for \$810 million. Except as thus stated, 3M denies the remaining allegations in Paragraph 25.

26. 3M admits that Augustine Medical Inc. received 510k clearance to market the Bair Hugger system Model 505 in 1996. Except as thus stated, 3M denies the remaining allegations in Paragraph 26.

27. 3M admits that Augustine Medical Inc. received 510k clearance to market Bair Hugger system Model 750 in 2000. Except as thus stated, 3M denies the remaining allegations in Paragraph 27.

28. Plaintiffs' allegations in Paragraph 28 are too vague, overbroad and generic for 3M to know whether it has sufficient information or knowledge to admit or deny the allegations. Responding further, 3M avers that Paragraph 28 contains legal conclusions to which no response is required. Except as thus stated, 3M denies the remaining allegations in Paragraph 28.

JURISDICTION AND VENUE

29. 3M admits only that this Court has jurisdiction over this action. Except as thus stated, 3M denies the remaining allegations in Paragraph 29.

30. 3M admits only that venue is proper in this Court and that it conducts substantial business in this judicial district. Except as thus stated, 3M denies the remaining allegations in Paragraph 30.

FACTUAL BACKGROUND

31. 3M admits the allegations in Paragraph 31.

32. 3M admits the allegations in Paragraph 32.

33. 3M admits the allegations in Paragraph 33.

34. 3M admits that in 2010, 3M entered into an agreement to acquire Arizant, Inc., and all rights to the Bair Hugger device, for \$810 million.

35. 3M admits the allegations in Paragraph 35.

36. 3M admits the allegations in Paragraph 36.

37. 3M admits that there are various types of Bair Hugger warming blankets. Responding further, 3M admits that different Bair Hugger blankets cover different portions of the patient's body and some are used under a patient's body. Except as thus stated, 3M denies the remaining allegations in Paragraph 37.

38. 3M admits only that Bair Hugger system models have a warming unit, hose and a single use disposable blanket. Except as thus stated, 3M denies the remaining allegations in Paragraph 38.

39. Plaintiffs' allegations in Paragraph 39 appear to seek to characterize a writing. In response, 3M states that such writings speak for themselves, and 3M denies that such writings have been completely or accurately characterized. Except as thus stated, 3M denies the remaining allegations in Paragraph 39.

40. 3M admits that it advertised the Bair Hugger system as safe and effective for patient warming. Except as thus stated, 3M denies the remaining allegations in Paragraph 40.

41. Plaintiffs' allegations in Paragraph 41 appear to seek to characterize a writing. In response, 3M states that such writings speak for themselves, and 3M denies that such writings have been completely or accurately characterized. Except as thus stated, 3M denies the remaining allegations in Paragraph 41.

42. 3M denies the allegations in Paragraph 42.

43. 3M denies the allegations in Paragraph 43.

44. 3M denies the allegations in Paragraph 44.

45. 3M denies the first sentence of Paragraph 45. Responding further, 3M avers that the regulatory filings with the FDA in 2000 related to the Bair Hugger warming system include certain references to the air filtration system and speak for themselves. 3M admits only that an air filter must arrest at least 99.97% of 0.3 μm particles to qualify as HEPA compliant. 3M otherwise denies the allegations in Paragraph 45.

46. 3M denies the allegations in Paragraph 46.

47. Plaintiffs' allegations in Paragraph 47 appear to seek to characterize a writing. In response, 3M states that such writings speak for themselves, and 3M denies that such writings have been completely or accurately characterized or contain accurate information. Responding further, 3M avers that not one scientific study (including those studies cited in the Master Complaint) has ever concluded that the Bair Hugger system actually causes or increases the risk of post-operative surgical site infections. Except as thus stated, 3M denies the remaining allegations in Paragraph 47.

48. 3M denies the allegations in Paragraph 48.

49. Plaintiffs' allegations in Paragraph 49 appear to seek to characterize a writing. In response, 3M states that such writings speak for themselves, and 3M denies that such writings have been completely or accurately characterized or contain accurate information. Responding further, 3M avers that not one scientific study (including those studies cited in the Master Complaint) has ever concluded that the Bair Hugger system actually causes or increases the risk of post-operative surgical site infections. Except as thus stated, 3M denies the remaining allegations in Paragraph 49.

50. 3M denies the allegations contained in Paragraph 50. Responding further, 3M avers that not one scientific study (including those studies cited in the Master Complaint) has ever concluded that the Bair Hugger system actually causes or increases the risk of post-operative surgical site infections.

51. 3M denies the allegations contained in Paragraph 51.

52. 3M denies the allegations contained in Paragraph 52.

53. Plaintiffs' allegations in Paragraph 53 appear to seek to characterize a writing. In response, 3M states that such writings speak for themselves, and 3M denies that such writings have been completely or accurately characterized. Except as thus stated, 3M denies the remaining allegations in Paragraph 53.

54. Plaintiffs' allegations in Paragraph 54 appear to seek to characterize a writing. In response, 3M states that such writings speak for themselves, and 3M denies that such writings have been completely or accurately characterized. Except as thus stated, 3M denies the remaining allegations in Paragraph 54.

55. 3M denies the allegations contained in Paragraph 55.

56. Plaintiffs' allegations in Paragraph 56 appear to seek to characterize a writing. In response, 3M states that such writings speak for themselves, and 3M denies that such writings have been completely or accurately characterized. 3M admits that www.fawfacts.com is a website maintained by 3M that contains information regarding forced air warming and the Bair Hugger system. Except as thus stated, 3M denies the remaining allegations in Paragraph 56.

57. 3M denies the allegations contained in Paragraph 57.

58. Plaintiffs' allegations in Paragraph 58 appear to seek to characterize recorded statements. In response, 3M states that such recorded statements speak for themselves, and 3M denies that such videos have been completely or

accurately characterized. Except as thus stated, 3M denies the remaining allegations in Paragraph 58.

59. Plaintiffs' allegations in Paragraph 59 appear to seek to characterize a writing. In response, 3M states that such writings speak for themselves, and 3M denies that such writings have been completely or accurately characterized. Except as thus stated, 3M denies the remaining allegations in Paragraph 59.

60. 3M denies the allegations contained in Paragraph 60. Responding further, 3M avers that not one scientific study (including those studies cited in the Master Complaint) has ever concluded that the Bair Hugger system actually causes or increases the risk of post-operative surgical site infections.

61. Plaintiffs' allegations in Paragraph 61 appear to seek to characterize a writing. In response, 3M states that such writings speak for themselves, and 3M denies that such writings have been completely or accurately characterized. 3M admits that the article titled "Operating Room: Normothermia reduces infection, length of stay" by Susan Cantrell, ELS in the July 2012 issue of *Healthcare Purchasing News* contains the statement by Ms. Greta R. Deutsch, public relations and communications specialist for Arizant: "Despite global recognition of forced-air warming's safety and effectiveness, and the wealth of research supporting its use in reducing the incidence of surgical infections by maintaining normothermia, some conductive-warming manufacturers have alleged that forced-air warming increases bacterial contamination of operating rooms or interrupts laminar airflow.

These accusations have no factual basis.” Except as thus stated, 3M denies the remaining allegations in Paragraph 61.

62. 3M denies the allegations in Paragraph 62.

63. Plaintiffs’ allegations in Paragraph 63 appear to seek to characterize a writing. In response, 3M states that such writings speak for themselves, and 3M denies that such writings have been completely or accurately characterized or contain accurate information. Responding further, 3M avers that not one scientific study (including those studies cited in Paragraph 63) has ever concluded that the Bair Hugger system actually causes or increases the risk of post-operative surgical site infections. Except as thus stated, 3M denies the remaining allegations in Paragraph 63.

64. 3M denies the allegations in Paragraph 64.

65. 3M denies the allegations in Paragraph 65.

66. 3M denies the allegations in Paragraph 66.

67. 3M denies the allegations in Paragraph 67.

68. 3M denies the allegations in Paragraph 68.

CLAIMS FOR RELIEF

COUNT 1 – NEGLIGENCE

69. 3M incorporates its answers and defenses to Paragraphs 1 – 68 by reference as if fully set forth herein.

70. 3M admits only that it designed, developed, tested, manufactured, assembled, inspected, packaged, promoted, marketed, designed, advertised, supplied and/or sold Bair Hugger systems to certain healthcare providers. Except as thus stated, 3M denies the remaining allegations in Paragraph 70.

71. 3M states that Paragraph 71 contains legal conclusions to which 3M is not required to respond. To the extent Paragraph 71 alleges any fault, wrongdoing or liability, 3M denies such allegations.

72. 3M states that Paragraph 72 contains legal conclusions to which 3M is not required to respond. To the extent Paragraph 72 alleges any fault, wrongdoing or liability, 3M denies such allegations.

73. 3M denies the allegations in Paragraph 73.

74. 3M denies the allegations in Paragraph 74.

75. 3M states that Paragraph 75 contains legal conclusions to which 3M is not required to respond. To the extent Paragraph 75 alleges any fault, wrongdoing or liability, 3M denies such allegations.

76. 3M denies the allegations in Paragraph 76.

77. 3M denies the allegations in Paragraph 77.

COUNT II – STRICT LIABILITY

78. 3M incorporates its answers and defenses to Paragraphs 1 – 77 by reference as if fully set forth herein.

79. 3M denies the allegations in Paragraph 79.

80. 3M denies the allegations in Paragraph 80.

81. 3M denies the allegations in Paragraph 81.

82. 3M denies the allegations in Paragraph 82.

A. Strict Liability – Failure to Warn

83. 3M incorporates its answers and defenses to Paragraphs 1 – 82 by reference as if fully set forth herein.

84. 3M admits only that it designed, manufactured, inspected, labeled, distributed, marketed, and sold the Bair Hugger system to certain healthcare providers. Except as thus stated, 3M denies the remaining allegations in Paragraph 84.

85. 3M admits only that it directly advertised or marketed the Bair Hugger system to certain healthcare providers. Except as thus stated, 3M denies the remaining allegations in Paragraph 85.

86. 3M states that Paragraph 86 contains legal conclusions to which 3M is not required to respond. To the extent Paragraph 86 alleges any fault, wrongdoing or liability, 3M denies such allegations.

87. 3M denies the allegations in Paragraph 87.

88. 3M denies the allegations in Paragraph 88.

89. 3M denies the allegations in Paragraph 89.

90. 3M denies the allegations in Paragraph 90.

B. Strict Liability – Defective Design and Manufacture

91. 3M incorporates its answers and defenses to Paragraphs 1 – 90 by reference as if fully set forth herein.

92. 3M admits that it manufactures and sells the Bair Hugger system. Except as thus admitted, 3M denies the remaining allegations in Paragraph 92.

93. 3M admits that the Bair Hugger system left 3M's manufacturing plant in the condition in which it was designed and manufactured. Except as thus stated, 3M denies the remaining allegations of Paragraph 93.

94. 3M denies the allegations in Paragraph 94.

95. 3M denies the allegations in Paragraph 95.

96. 3M denies the allegations in Paragraph 96.

97. 3M denies the allegations in Paragraph 97.

98. 3M is without sufficient information or knowledge to admit or deny whether the Bair Hugger system reached Plaintiffs without substantial change after it left 3M's control. Except as thus stated, 3M denies the remaining allegations of Paragraph 98.

99. 3M denies the allegations in Paragraph 99.

100. 3M denies the allegations in Paragraph 100.

COUNT III – BREACH OF EXPRESS WARRANTY

101. 3M incorporates its answers and defenses to Paragraphs 1 – 100 by reference as if fully set forth herein.

102. 3M admits only that its labeling contains its representations about the intended use of the Bair Hugger system. Except as thus stated, 3M denies any express representations to Plaintiffs and denies the remaining allegations in Paragraph 102.

103. 3M denies the allegations in Paragraph 103.

104. 3M denies the allegations in Paragraph 104.

105. 3M denies the allegations in Paragraph 105.

106. 3M denies the allegations in Paragraph 106.

COUNT IV – BREACH OF IMPLIED WARRANTY

107. 3M incorporates its answers and defenses to Paragraphs 1 – 106 by reference as if fully set forth herein.

108. 3M admits only that it designed, manufactured, inspected, labeled, distributed, marketed, and sold the Bair Hugger system to certain healthcare providers. Except as thus stated, 3M denies the remaining allegations in Paragraph 108.

109. 3M states that Paragraph 109 contains legal conclusions to which 3M is not required to respond. To the extent required to respond, 3M admits only that it knew of the Bair Hugger system's intended use. Except as thus stated, 3M denies the remaining allegations in Paragraph 109.

110. 3M admits only that it was aware the Bair Hugger system would be used with a physician's order during surgical procedures. Except as thus stated, 3M denies the remaining allegations in Paragraph 110.

111. 3M denies the allegations in Paragraph 111.

112. 3M is without sufficient information or knowledge to admit or deny whether the Bair Hugger system reached Plaintiffs without substantial change after it left 3M's control. Except as thus stated, 3M denies the remaining allegations in Paragraph 112.

113. 3M denies the allegations in Paragraph 113.

114. 3M denies the allegations in Paragraph 114.

115. 3M denies the allegations in Paragraph 115.

116. 3M denies the allegations in Paragraph 116.

117. 3M denies the allegations in Paragraph 117.

118. 3M denies the allegations in Paragraph 118.

119. 3M denies the allegations in Paragraph 119.

120. 3M denies the allegations in Paragraph 120.

**COUNT V – VIOLATION OF THE MINNESOTA
PREVENTION OF CONSUMER FRAUD ACT**

121. 3M incorporates its answers and defenses to Paragraphs 1 – 120 by reference as if fully set forth herein.

122. Paragraph 122 makes no factual assertions or allegations to which 3M is required to respond.

123. 3M states that Paragraph 123 contains legal conclusions to which 3M is not required to respond. To the extent required to respond, 3M denies the allegations in Paragraph 123.

124. 3M states that Paragraph 124 contains legal conclusions to which 3M is not required to respond. To the extent required to respond, 3M denies the allegations in Paragraph 124.

125. 3M denies the allegations in Paragraph 125.

126. 3M denies the allegations in Paragraph 126.

127. 3M denies the allegations in Paragraph 127.

128. 3M denies the allegations in Paragraph 128.

129. 3M denies the allegations in Paragraph 129.

130. 3M denies the allegations in Paragraph 130.

**COUNT VI – VIOLATION OF THE MINNESOTA
DECEPTIVE TRADE PRACTICES ACT**

131. 3M incorporates its answers and defenses to Paragraphs 1 – 130 by reference as if fully set forth herein.

132. Paragraph 132 makes no factual assertions or allegations to which 3M is required to respond.

133. 3M denies the allegations in Paragraph 133.

134. 3M denies the allegations in Paragraph 134.

**COUNT VII – VIOLATION OF THE MINNESOTA
UNLAWFUL TRADE PRACTICES ACT**

135. 3M incorporates its answers and defenses to Paragraphs 1 – 134 by reference as if fully set forth herein.

136. Paragraph 136 makes no factual assertions or allegations to which 3M is required to respond.

137. 3M states that Paragraph 137 contains legal conclusions to which 3M is not required to respond. To the extent required to respond, 3M denies the allegations in Paragraph 137.

138. 3M states that Paragraph 138 contains legal conclusions to which 3M is not required to respond. To the extent required to respond, 3M denies the allegations in Paragraph 138.

139. 3M denies the allegations in Paragraph 139.

140. 3M denies the allegations in Paragraph 140.

141. 3M denies the allegations in Paragraph 141.

142. 3M denies the allegations in Paragraph 142.

143. 3M denies the allegations in Paragraph 143.

144. 3M denies the allegations in Paragraph 144.

**COUNT VIII – VIOLATION OF THE
MINNESOTA FALSE ADVERTISING ACT**

145. 3M incorporates its answers and defenses to Paragraphs 1 – 144 by reference as if fully set forth herein.

146. Paragraph 146 makes no factual assertions or allegations to which 3M is required to respond.

147. 3M denies the allegations in Paragraph 147.

148. 3M denies the allegations in Paragraph 148.

149. 3M denies the allegations in Paragraph 149.

150. 3M denies the allegations in Paragraph 150.

151. 3M denies the allegations in Paragraph 151.

152. 3M denies the allegations in Paragraph 152.

**COUNT IX – CONSUMER FRAUD AND/OR UNFAIR AND
DECEPTIVE TRADE PRACTICES UNDER STATE LAW**

153. 3M incorporates its answers and defenses to Paragraphs 1 – 152 by reference as if fully set forth herein.

154. Paragraph 154 makes no factual assertions or allegations to which 3M is required to respond.

155. Paragraph 155 makes no factual assertions or allegations to which 3M is required to respond.

156. 3M denies the allegations in Paragraph 156.

157. 3M denies the allegations in Paragraph 157.

158. 3M denies the allegations in Paragraph 158.

159. 3M denies the allegations in Paragraph 159.

160. 3M denies the allegations in Paragraph 160.

161. 3M states that Paragraph 161 contains legal conclusions to which 3M is not required to respond. To the extent required to respond, 3M denies the allegations in Paragraph 161.

162. 3M denies the allegations in Paragraph 162.

163. 3M denies the allegations in Paragraph 163.

164. 3M denies the allegations in Paragraph 164.

165. 3M denies the allegations in Paragraph 165.

166. 3M denies the allegations in Paragraph 166.

167. 3M denies the allegations in Paragraph 167.

COUNT X – NEGLIGENT MISREPRESENTATION

168. 3M incorporates its answers and defenses to Paragraphs 1 – 167 by reference as if fully set forth herein.

169. 3M denies the allegations in Paragraph 169.

170. 3M denies the allegations in Paragraph 170.

171. 3M denies the allegations in Paragraph 171.

172. 3M denies the allegations in Paragraph 172.

173. 3M denies the allegations in Paragraph 173.

174. 3M denies the allegations in Paragraph 174.

175. 3M denies the allegations in Paragraph 175.

COUNT XI – FRAUDULENT MISREPRESENTATION

176. 3M incorporates its answers and defenses to Paragraphs 1 – 175 by reference as if fully set forth herein.

177. 3M denies the allegations in Paragraph 177.

178. 3M denies the allegations in Paragraph 178.

179. 3M denies the allegations in Paragraph 179.

180. 3M denies the allegations in Paragraph 180.

181. 3M denies the allegations in Paragraph 181.

182. 3M denies the allegations in Paragraph 182.

183. 3M denies the allegations in Paragraph 183.

184. 3M denies the allegations in Paragraph 184.

COUNT XII – FRAUDULENT CONCEALMENT

185. 3M incorporates its answers and defenses to Paragraphs 1 – 184 by reference as if fully set forth herein.

186. 3M denies the allegations in Paragraph 186.

187. 3M denies the allegations in Paragraph 187.

188. 3M denies the allegations in Paragraph 188.

189. 3M denies the allegations in Paragraph 189.

190. 3M denies the allegations in Paragraph 190.

191. 3M denies the allegations in Paragraph 191.

192. 3M denies the allegations in Paragraph 192.

COUNT XIII – LOSS OF CONSORTIUM

193. 3M incorporates its answers and defenses to Paragraphs 1 – 192 by reference as if fully set forth herein.

194. 3M is without sufficient information or knowledge to admit or deny the allegations in Paragraph 194. If required to respond, 3M denies the allegations in Paragraph 194.

195. 3M denies the allegations in Paragraph 195.

COUNT XIV – UNJUST ENRICHMENT

196. 3M incorporates its answers and defenses to Paragraphs 1 – 195 by reference as if fully set forth herein.

197. 3M denies the allegations in Paragraph 197.

198. 3M denies the allegations in Paragraph 198.

PRAYER

Answering the unnumbered “Prayer for Relief” Paragraph following Paragraph 198, 3M denies it is liable to Plaintiffs in any manner whatsoever, and denies that Plaintiffs are entitled to any of the relief requested.

AFFIRMATIVE DEFENSES

Without assuming any burden it would not otherwise bear, 3M asserts the following Affirmative Defenses or matters of avoidance:

FIRST DEFENSE

The Master Complaint fails to state, in whole or in part, a claim upon which relief can be granted.

SECOND DEFENSE

The Master Complaint may fail to join necessary and proper parties.

THIRD DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the applicable statutes of limitations and/or repose.

FOURTH DEFENSE

Plaintiffs' alleged injuries were not proximately caused by any act or omission of the part of 3M.

FIFTH DEFENSE

In the event Plaintiffs have sustained damages as alleged in the Master Complaint, which 3M denies, discovery or investigation may reveal that Plaintiffs' claims are barred or reduced, in whole in or in part, by the doctrines of contributory and/or comparative negligence.

SIXTH DEFENSE

If Plaintiffs suffered any injuries or incurred any damages, which 3M denies, discovery or investigation may reveal the same was caused, in whole or in part, by: (1) products which were not manufactured by 3M; or (2) the acts or omissions of persons or entities other than 3M and over whom 3M had no

control; (3) events over which 3M had no control; or (4) superseding or intervening causes over which 3M had no control. 3M's liability, if any, to Plaintiffs for any damages, including non-economic damages, should be diminished, reduced, and/or offset on the basis of the fault and responsibility of such other persons and/or entities.

SEVENTH DEFENSE

Discovery or investigation may reveal injuries, damages, and/or losses, if any, sustained by Plaintiffs were the result of Plaintiffs' unforeseeable pre-existing medical conditions and/or an idiosyncratic reaction by Plaintiffs which were not reasonably foreseeable and which was not the result of any conduct or negligence on the part of 3M, nor the result of any defect in any product manufactured by 3M. Accordingly, 3M cannot be held liable for Plaintiffs' claims.

EIGHTH DEFENSE

There exists no proximate causation between any alleged act, omission, or breach of duty by 3M and Plaintiffs' alleged damages, injuries, and/or losses. Such damages, injuries, and/or losses, if any, were the result of conduct of persons or entities other than 3M.

NINTH DEFENSE

Discovery or investigation may reveal Plaintiffs have failed to mitigate the damage, if any, sustained and have failed to exercise reasonable care to avoid the consequences of harms, if any, in that, among other things, Plaintiffs may have

failed to use reasonable diligence in caring for any injury, failed to use reasonable means to prevent aggravation of any injury, and failed to take reasonable precautions to reduce any injury and damage.

TENTH DEFENSE

Any duty to warn Plaintiffs of any risks or hazards associated with the subject medical device was discharged by providing adequate and sufficient warnings to Plaintiffs' physicians and other health care providers, and therefore the sophisticated user and/or learned intermediary doctrine bars Plaintiffs' recovery of damages.

ELEVENTH DEFENSE

Plaintiffs' claims are barred, in whole or in part, because Plaintiffs and/or Plaintiffs' medical providers did not reasonably rely on any act, omission, or representation made by 3M.

TWELFTH DEFENSE

In the event Plaintiffs have sustained damages as alleged in the Master Complaint, which is denied, discovery or investigation may reveal that Plaintiffs' claims are barred, in whole or in part, by the misuse, abuse, modification, alteration, or other change in the product after 3M relinquished possession of and control over the subject product.

THIRTEENTH DEFENSE

Plaintiffs fail to plead fraud with particularity as required by the Federal Rules of Civil Procedure 9(b) and any other applicable state statute.

FOURTEENTH DEFENSE

Plaintiff's claims are barred in whole or in part by the doctrines of estoppel, collateral estoppel, laches, and waiver.

FIFTEENTH DEFENSE

Plaintiffs' claims may be barred due to the spoliation of evidence.

SIXTEENTH DEFENSE

The design, manufacture, labeling and packaging of the Bair Hugger warming system were in conformity with the "state of the art" existing at the time of such design, manufacture, labeling and packaging. Liability (including, but not limited to, strict liability) may not be imposed as to a properly manufactured prescription medical device distributed with information regarding the risks of which the manufacturer knew at the time of the manufacture, and liability may not be imposed for untold risks not known at the time of such design, manufacture, and sale of the subject medical device.

SEVENTEENTH DEFENSE

Plaintiffs' claims are barred in whole or in part because the product at issue was not unreasonably dangerous or defective at the time it left the manufacturer's possession.

EIGHTEENTH DEFENSE

To the extent the claims asserted in the Master Complaint are based on a theory providing for liability without proof of defect and proof of causation, the claims violate 3M's rights under the United States Constitution and analogous provisions of Constitutions of the 50 States.

NINETEENTH DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the Commerce Clause of the United States Constitution because they purport to regulate interstate commerce and impermissibly place an undue burden on interstate commerce.

TWENTIETH DEFENSE

3M denies any negligence on its part and shows that, at all times relevant to Plaintiffs' Master Complaint, it met or exceeded the requisite standard of care.

TWENTY-FIRST DEFENSE

3M and its employees and agents met all applicable duties and acted reasonably and in good faith at all times material herein, based on all relevant facts and circumstances known by them at the time they so acted.

TWENTY-SECOND DEFENSE

Plaintiffs' claims are barred because the social utility or benefits of the product at issue outweighed the product's risk, if any.

TWENTY-THIRD DEFENSE

Plaintiffs' claims are barred, in whole or in part, because the product at all times relevant hereto complied with all applicable laws and regulations to which the product was in any respect subject, including but not limited to the deference that the common law gives to discretionary action by the Food and Drug Administration.

TWENTY-FOURTH DEFENSE

The conduct of 3M and the subject product conformed with the Federal Food, Drug, and Cosmetic Act and the requirements of the Food and Drug Administration. Moreover, 3M's activities conformed with state and federal statutes, regulations, and industry standards based upon the state of knowledge existing at the relevant time alleged in the Master Complaint.

TWENTY-FIFTH DEFENSE

Plaintiffs' claims may be barred, in whole or in part, by the doctrine of federal preemption.

TWENTY-SIXTH DEFENSE

Any injury sustained by Plaintiffs is the result of an unforeseeable series of events over which 3M had no control, and as such 3M cannot be held liable.

TWENTY-SEVENTH DEFENSE

Plaintiff's warranty-based claims are barred in whole or in part on the grounds that 3M did not make or breach any warranties applicable to Plaintiffs.

TWENTY-EIGHTH DEFENSE

Plaintiffs' warranty-based claims are barred in whole or in part by Plaintiffs' lack of reliance upon any such warranties.

TWENTY-NINTH DEFENSE

Plaintiffs' warranty-based claims are barred in whole or in part by lack of privity between Plaintiffs and 3M.

THIRTIETH DEFENSE

3M did not have any opportunity to cure any alleged "defect" in the product at issue, if any such "defect" existed, which is specifically denied; thus, Plaintiffs are precluded from recovering from 3M for breach of warranty.

THIRTY-FIRST DEFENSE

Plaintiffs' warranty claims are barred due to (1) Plaintiffs' failure to give timely notice as to any alleged breach of warranty; (2) Plaintiffs' failure to satisfy all conditions precedent or subsequent to the enforcement of any such alleged warranty; and/or (3) the fact that any such alleged warranty was appropriately disclaimed, excluded or modified. 3M further specifically plead as to any breach of warranty claim all affirmative defenses under the Uniform Commercial Code.

THIRTY-SECOND DEFENSE

Plaintiffs' claims are barred, in whole or in part, by applicable state common law and state statutory law regarding products liability as may be applicable based on the evidence presented in this case.

THIRTY-THIRD DEFENSE

Plaintiffs may not recover on the claims pleaded in the Master Complaint because the damages sought are too speculative and remote.

THIRTY-FOURTH DEFENSE

Plaintiffs' claims for equitable relief are barred because Plaintiffs have an adequate remedy at law.

THIRTY-FIFTH DEFENSE

Plaintiffs are not entitled to the equitable relief requested in the Master Complaint because the hardship that would be imposed on 3M by the relief is greatly disproportionate to any hardship that Plaintiffs might suffer in its absence.

THIRTY-SIXTH DEFENSE

Plaintiffs are not entitled to the equitable relief requested in the Master Complaint because the Court lacks any sufficiently certain, nonspeculative basis for fashioning such relief.

THIRTY-SEVENTH DEFENSE

Plaintiff's claims are barred, in whole or in part, by the principles set forth in the Restatement (Second) of Torts § 388, Comment n, and any similar doctrines and/or principles in the Restatement (Third) of Torts.

THIRTY-EIGHTH DEFENSE

Plaintiff's claims are barred, in whole or in part, by the principles set forth in the Restatement (Second) of Torts § 402a, Comments j and k, and the Restatement (Third) of Torts: Products Liability §§ 4 and 6.

THIRTY-NINTH DEFENSE

Plaintiff's design defect claims are barred pursuant to Section 6(c) of the Restatement (Third) of Torts: Products Liability, because the device at issue provides significant benefit to ascertainable patient classes, who derive substantial benefits from the intended effects.

FORTIETH DEFENSE

The First Amendment of the United States Constitution and similar provisions in applicable state constitutions protect the promotion of products sold or manufactured by 3M and their parents, subsidiaries or affiliates.

FORTY-FIRST DEFENSE

If any use of 3M's product was a proximate cause of any injury to Plaintiffs, which 3M specifically denies, then said use would have been so minimal that it would be insufficient to establish to a reasonable degree of

medical probability that 3M's product was the proximate cause of Plaintiffs' alleged injuries.

FORTY-SECOND DEFENSE

Plaintiffs' claims are barred because the relevant product was consistent with or exceeded consumer expectations.

FORTY-THIRD DEFENSE

3M specifically pleads and incorporates by reference as an affirmative defense all applicable caps, limitations and set-offs upon any award of damages, both compensatory and punitive, which are provided by law.

FORTY-FOURTH DEFENSE

3M pleads by way of affirmative defense that, to the extent Plaintiffs seeks recovery for medical bills, expenses and services that were incurred, but which were never charged to Plaintiffs and thus were never paid by Plaintiffs because they exceed the amount authorized by Medicare, Medicaid or any health care plan, Plaintiffs are not entitled to recover these amounts.

FORTY-FIFTH DEFENSE

Plaintiffs are not entitled to satisfaction under the consumer protection laws of Minnesota or any other state because Plaintiffs cannot satisfy the elements of these statutes and because Plaintiffs lack standing to assert claims under these statutes.

FORTY-SIXTH DEFENSE

While denying at all times Plaintiffs have stated a valid claim under Minnesota consumer protection statutes or the consumer protection statutes of any other state, to the extent such claims are found to exist, 3M pleads all defenses available under those statutes and states that any such claims are limited by the provisions of the statutes.

FORTHY-SEVENTH DEFENSE

Plaintiffs' claims under the Minnesota Private Attorney General Statute, § 8.31, fail. This action is not maintained for the public benefit. Plaintiffs seek money damages, there are no ongoing misrepresentations, and the Master Complaint lacks sufficient deterrent effect.

FORTY-EIGHTH DEFENSE

3M hereby gives notice that it intends to rely on any additional affirmative defenses that become available or apparent during discovery or prior to trial, and thus 3M reserves the right to amend this Master Answer to assert such defenses.

FORTY-NINTH DEFENSE

To the extent not incorporated above, 3M raises all affirmative defenses applicable under Minnesota law and the laws of other states, as referenced in the Master Complaint.

FIFTIETH DEFENSE

3M expressly preserves, and does not knowingly or intentionally waive, any other affirmative defenses set forth in Fed. R. Civ. P. 8, or any applicable state law, which discovery may reveal to be applicable, or any other matter constituting an avoidance or affirmative defense.

FIFTY-FIRST DEFENSE

3M adopts and incorporates by reference herein any affirmative defenses that have been or may be raised by any other Defendant named in or later joined to this action.

WHEREFORE, 3M respectfully prays for relief and judgment against Plaintiffs as follows:

1. That Plaintiffs take nothing by reason of this Master Complaint;
2. That judgment be entered for 3M and against Plaintiffs on each and every claim set forth in the Master Complaint;
3. That 3M recover its costs of suit; and
4. For such further and other relief as the Court deems just and proper.

JURY DEMAND

3M hereby requests a jury trial as to all claims triable in this action.

Dated: July 8, 2016

Respectfully submitted,

s/Jerry W. Blackwell

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